

### **Remarks/Arguments**

After entry of this Amendment, claims 1, 3-8, 10-12, 15-17, 21, 24-25, 36, and 38-41, as amended, will be pending in the application for the Examiner's review and consideration. Claims 2, 9, 13-14, 18-20, 22, 23 and 26-35 have been canceled without prejudice. The right to prosecute the subject matter of any of the canceled claims in this or in a continuation, continuation-in-part, or divisional application is hereby expressly reserved.

#### **Claim Amendments:**

New claims 38-41 have been added. These claims are supported, for example, on page 6, lines 22-29, and page 8, lines 18-29. The claims are also supported on page 8, lines 3-8 and 13-17, which recites the optional inclusion of a non-toxic zinc salt or tyrosine in the composition. "If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." M.P.E.P. § 2173.05(i).

Accordingly, no new matter has been added to the claims by these amendments.

#### **Non-obviousness of New Claims 38-41:**

Claims 1, 3-8, 10-12, 15-17, 21, 24-25, and 36 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 4,938,969 to Schinitzky and Meisner ("Schinitzky & Meisner") in view of U.S. Patent No. 5,804,594 to Murad ("Murad"); U.S. Patent No. 5,902,591 to Herstein ("Herstein") or U.S. Patent No. 5,140,043 to Darr and Pinnell ("Darr"); THE MERCK INDEX, entry 855 (9th ed. 1976) ("Merck Index"); and J.P. Yuan & F. Chen, *J. Agric. Food Chem.*, 46: 5078-82 (1998) ("Yuan"). These rejections were addressed in an Amendment filed on October 7, 2009. In order to expedite prosecution of the application, presented below are arguments in support of the patentability of new claims 38-41 over these references.

Claims 38-41 recite compositions comprising: at least 10% (w/v) ascorbic acid; approximately 5% to 20% (w/v) glucosamine; and water, wherein: the composition has a pH of about 3.5 to about 4.1; the composition does not comprise tyrosine; and the composition does not comprise a non-toxic zinc salt.

1. The references cited by the Office, even when combined, do not teach or suggest all of the recitations of claims 38-41
  - a. "the composition does not comprise tyrosine"

None of Schinitsky & Meisner, Murad, Herstein, Darr, Merck Index or Yuan teaches or suggests an ascorbic acid composition as recited in the claims, that does not comprise tyrosine.

To the contrary, both Schinitsky & Meisner and Murad stress the importance of the inclusion of an amino acid, such as tyrosine. Every composition referred to in Schinitsky & Meisner contains tyrosine as an ingredient. (*See, e.g.*, Schinitsky & Meisner, col. 3, Table 1). In addition, Murad underscores the function of an amino acid (such as tyrosine) by stating that the amino acid is effective to thicken the skin. (*See* Murad, col. 6, ll. 9-33).

b. “the composition does not comprise a non-toxic zinc salt”

None of Schinitsky & Meisner, Murad, Herstein, Darr, Merck Index or Yuan teaches or suggests an ascorbic acid composition as recited in claims 38-41, that does not comprise a non-toxic zinc salt.

Schinitsky & Meisner states that “an essential ingredient in the present composition is a non-toxic, water soluble zinc salt . . . without zinc sulfate in the present formation, we have found no beneficial effect.” (Schinitsky & Meisner, col. 2, ll. 54-56). Elimination of an essential ingredient from the primary reference renders the combination of references used in the rejection improper. In addition, Murad underscores the function of the transition metal compound by stating that the transition metal compound is effective to bind collagen and elastic tissue to rebuild the skin. (*See* Murad, col. 6, ll. 34-52).

c. “the composition has a pH of about 3.5 to about 4.1”

None of Schinitsky & Meisner, Murad, Merck Index or Yuan teaches or suggests a composition comprising ascorbic acid that has a pH of about 3.5 to about 4.1, as recited in claims 38-41. The Office cites Herstein or Darr to provide the missing teaching of the recited pH. This is unavailing for at least the following reasons.

The Declaration of Dr. Lorraine Faxon Meisner under 37 C.F.R. § 1.132 submitted on October 7, 2009 (“Meisner Declaration”) clearly establishes through several peer-reviewed journal articles that, at the time of the invention, it would have been entirely unexpected that an ascorbic acid composition would be stable enough for use in a topical composition at a pH of about 3.5 to about 4.1. (Meisner Declaration, ¶¶ 11-12). Dr. Meisner’s conclusion is supported not only by the Bauernfeind, Hajratwala, and Kassem articles cited in her Declaration, but also by Herstein and Darr, which were cited by the Office.

Herstein and Darr both acknowledge the instability of ascorbic acid compositions at the pH range recited in the claims. For example, Herstein teaches that emulsions of ascorbic acid having a pH within the range of 3.5 to 4.1 are unstable if they lack an organoclay stabilizer: “As can be seen from the data, the physical appearance of the emulsion initially is acceptable and remains acceptable (no breaking of the emulsion) after 25 days. Without the organoclay ingredient, the emulsion would begin to break down after a few days, i.e., 2-3 days.” (Herstein, col. 13, ll. 35-41). In addition, Darr stresses the importance of maintaining the pH of an ascorbic acid composition at “no more than about 3 to 3.5, preferably no more than about 2.5” in order to “ensure[] that greater than 82% of the ascorbic acid remains in the protonated, uncharged form,” which “removes the ionic repulsion of the two oxygen groups, thus stabilizing the molecule.” (Darr, col. 3, ll. 29-30, col. 4, ll. 7-18).

Therefore, neither Herstein nor Darr, when combined with the teachings of Schinitzky & Meisner, Murad, Merck Index and/or Yuan, teaches or suggests the recited compositions having a pH of about 3.5 to about 4.1.

For these reasons, any rejection of claims 38-41 under 35 U.S.C. § 103(a) as obvious over Schinitzky & Meisner in view of Murad, Herstein or Darr, Merck Index, and Yuan is obviated.

*Conclusion:*

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the Examiner is invited to contact the undersigned at (212) 497-7731 to discuss the same.

No fee is believed to be due for the submission of this Amendment. Should any fees be required, please charge all such fees to Wilson, Sonsini, Goodrich & Rosati Deposit Account No. 23-2415 (36091-701.302).

Respectfully submitted,

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By: /Gina R. Gencarelli/  
Gina R. Gencarelli  
Reg. No. 59,729

WILSON, SONSINI, GOODRICH & ROSATI PC  
650 Page Mill Road  
Palo Alto, CA 94304  
Phone: (650) 493-9300  
Fax: (650) 493-6811  
**Customer No. 21971**